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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,072	08/06/2003	James Lousararian	P2205.01CIP2	9838

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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SANTA ROSA, CA 95403

EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

NOTIFICATION DATE	DELIVERY MODE
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07/21/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary

Application No.

10/636,072

Applicant(s)

LOUSARARIAN ET AL.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17 and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/17/2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-8, 48, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cummins** (U.S. Patent No. **7,008,435**) in view of Williamson, IV et al., hereinafter **Williamson** (U.S. Patent No. **5,972,004**).

Claims 1, 3-8, 48, 50: Cummins discloses an individual staple **10** having a proximal end adapted for individual attachment to a single-staple delivery device, the staple having a plurality of distally extending prongs commonly connected to the proximal end

Art Unit: 3731

at a crown and having tissue-piercing distal tips with sufficient stiffness to pierce tissue solely in response to a distal force applied at the proximal end, and a pledget **12** being pre-attached to the staple (before the staple engages tissue) and being embraced by the prongs, the pledget having preformed edges or peripheral notches **16** configured to be frictionally engaged by and between the prongs to capture and retain the pledget on the staple and to enable the combined staple and attached pledget to be advanced together by a single-staple delivery device, whereby when the prongs of the staple are engaged with tissue, the pledget will be disposed and retained (Figures 1-6). The pledget may have a plurality of peripherally extending tabs configured to be received between said plurality of prongs (tabs on either side of edges or slots **16** in Figure 1) or The pledget comprises a bioabsorbable woven or non-woven fabric material, and a polyester or polymer sheet (col. 3, lines 41-44).

Cummins does not expressly disclose the pledget being carried by the staple.

Williamson teaches a pledget **P** that may be placed on a staple ("fastener") before being placed on the tool (Figures 4 and 24, col. 12, lines 53-59). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a staple that carries a pledget, as taught by Williamson, to Cummins in order to ensure and maintain a secure engagement between the two elements when fastened against tissue.

Art Unit: 3731

4. Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cummins** (U.S. Patent No. **7,008,435**) in view of **Williamson** (U.S. Patent No. **5,972,004**), as applied to claim 1 above, and further in view of **Dalessandro** (U.S. Patent No. **6,273,897**).

Claims 9-17: Cummins and Williamson disclose the claimed device except for the pledget having a physiologically active agent adapted to be released over a predetermined time interval or comprising a coating or being impregnated in the pledget, or being an anti-microbial/antiseptic agent, or being an agent that inhibits intraluminal clotting or promotes extraluminal clotting.

Dalessandro teaches a bioabsorbable pledget (or “buttress”) **52** containing physiologically active agents that are released over a predetermined time interval, anti-microbial or anti-septic agents, agents that inhibit intraluminal clotting or promote extraluminal clotting, or agents that comprise a coating or are impregnated in said pledget (Figures 4-6, col. 5, lines 24 to col. 7, line 55). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a pledget comprising the above materials and agents, as taught by Dalessandro, to Cummins and Williamson since they are well known in the art for their biocompatibility and other benefits that promote healing.

Art Unit: 3731

5. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Cummins** (U.S. Patent No. **7,008,435**) in view of **Williamson** (U.S. Patent No. **5,972,004**), as applied to claim 1 above, and further in view of **Ginn** (U.S. Patent No. **6,277,140**).

Claim 49: Cummins and Williamson disclose the claimed device, except for the crown including distally extending tabs or webs adapted to bear against the pledget.

Ginn teaches a staple **62** having four prongs **76** and being commonly connected at a crown **70** including distally extending tabs or webs (near **74**) adapted to bear against a pledget (Figure 28). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the distally extending tabs or webs, as taught by Ginn, to Cummins and Williamson in order to create a secure engagement between the pledget and the staple.

Response to Arguments

6. Applicant's arguments filed 06/17/2008 have been fully considered but they are not persuasive.

7. Applicant argues that Cummins fails to disclose the proximal end of the staple being configured to enable the delivery device to control closure of the staple prongs solely by manipulation of the proximal end of the staple. However, Cummins discloses that a staple-firing mechanism drives the staple 10 towards the free end 28, or from the proximal end to the distal end (col. 3, lines 60-65 and Figures 4-6), and therefore the

Art Unit: 3731

proximal end of the staple is able to or configured to be manipulated solely at its proximal end for controlling closure of the staple prongs.

8. The applicant also argues that the pledget is not pre-attached to the staple in Cummins. However, in Figure 3 the staple and the pledget are pre-attached, prior to engaging tissue -- the staple is engaged with or attached to the pledget, or is advanced as a unit with the pledget first before being attached to tissue, and therefore may be considered to be advanced together in order to engage tissue. In other words, since the pledget is positioned in between the staple and the tissue, the staple must be pre-attached with the pledget during advancement before engaging the tissue.

9. In addition, the applicant argues that Cummins does not disclose a pledget having edges configured to be frictionally engaged by and between the prongs to capture and retain the pledget on the staple. However, for example in Figure 6b it is shown that Cummins discloses the pledget being clearly engaged by and between the top portions of the staple prongs.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731